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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,125	01/20/2004	Per Antonsson	003301-106	6671

21839 7590 12/29/2005

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EXAMINER	
SALIMI, ALI REZA	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/759,125	ANTONSSON ET AL.	
	Examiner	Art Unit	
	A R. Salimi	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

This is a response to the amendment 11/23/05. Claims 1-5 have been amended and are pending.

Please note any ground of rejection that has not been repeated is removed.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, for reasons of record advanced in the previous Office Action mailed 5/23/05. Applicant asserts that the now amended claim clarifies the intended L1 protein. Applicant's argument as part of amendment filed 11/23/05 has been considered fully, but they are not persuasive. Applicants are reminded that substituting one indefinite claim for another is not advanced in prosecution. The intended metes and bounds of the second so called "modified" L1 protein that is fused to the L1 protein of claim 1 is not defined. The rejection is maintained.

Claim Rejections - 35 USC § 112

Claims 1-2, 4-5 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record advanced in the previous Office Action mailed 5/23/05. Applicants argue that they have formed a site-specific modification to HPV-16 L1 protein and abolish major type specific epitopes. Moreover, Applicants assert that they have provided a manuscript that is not yet published to further explain the invention. Applicant's argument as part of amendment filed 11/23/05 has been considered fully, but they are not persuasive. First regarding the non-published manuscript, although the Office has looked at the manuscript, the manuscript has no bearing on the

patentability of the now claimed invention. The manuscript is not a formal declaration, and is not published. Applicants have not followed formal procedure for submitting an Information Disclosure Statement or Declaration. Thus, the manuscript has no bearing on the argument presented, until and unless it is officially submitted. Additionally, Applicants argument regarding the scope of the enablement is rather convoluted. None of the limitations that are being argued is present in the claims. Office has already mentioned that Application is enabled for certain substitution of HPV-16 L1 protein, the question is whether the specification has taught for broad limitations of the now claimed invention. The answer is clearly, No. The sequences of various papillomaviruses are different from one another, and there are no common structures that exist between all L1 proteins, substituting one set of amino acids in a well known L1 protein does not translate into modification of all HPV L1 capsid protein. Applicants cannot rely on the knowledge of those skilled in the art to enable the claims without providing adequate teaching. The rejection is maintained.

Claim Rejections - 35 USC § 112

Claims 1-2, 4-5 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record advanced in the previous Office Action mailed 5/23/05. Applicants do not provide a separate argument for the Written Description rejection and provide one argument under the enablement. This is not permitted, the issue of written description is vastly different than enablement. Applicants are referred to written description guidelines that can easily be found at the USPTO web site. In the meanwhile the rejection is maintained until reasonable argument is provided. The rejection is maintained.

Claim Rejections - 35 USC § 102

Claims 1-2, 4-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Bloch et al (WO 97/46693), for reasons of record advanced in the previous Office Action mailed 5/23/05. Applicants argue that Bloch discloses a different genetic construct from that of the presently claimed invention. Applicant's argument as part of amendment filed 11/23/05 has been considered fully, but they are not persuasive. The above cited patent taught a modified L1 protein product, and the same product is now being claimed. The product taught by Bloch meets the broad limitations of the claimed product. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The rejection is maintained.

Claim Rejections - 35 USC § 103

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over, Christensen et al (J. of General Virology, 1994, Vol. 75, pages 2271-2276), and Touze et al (Nucleic Acid Research, 1998, Vol. 26, No. 5, pages 1317-1323) for reasons of record advanced in the previous Office Action mailed 5/23/05. Applicants argue that Christensen fails to disclose the position or identity of the neutralizing epitopes in protein L1, and deficiencies of Christensen et al is not corrected by teaching of Touze et al. Applicant's argument as part of amendment filed 11/23/05 has been considered fully, but they are not persuasive. Applicants understanding of obviousness is misplaced. First, Applicant has not identified position of neutralizing epitopes within the

broad scope of the claimed invention, and has actually used the same method as Christensen to identify HPV-16 L1 epitopes. In addition, Applicants had ample motivation in view of the above teaching to modify the epitopes to decrease antibody response to the L1 and wherein the VLP can be utilized in gene therapy wherein heterologous moieties inside the VLPs could be utilized in treating diseases. Moreover, in view of teaching Applicants could not have anticipated any unexpected results, as none have been provided. In view of the above teaching the invention as a whole is obvious. The rejection is maintained.

New Grounds of Rejection:

Claim Rejections - 35 USC § 112

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite for recitation of "site-specific", the intended "site-specific" substitution is not identified. This affects dependent claims 2-5.

Claim 2 is vague, indefinite and unclear for recitation of " homologous to the L1 protein", the intended homologous protein(s) is/are not defined. Homology or sequence similarity can be calculated by a variety of different methods, whereby the calculated identity between two sequences will be quite different depending on the algorithm used for calculation. Since no art-recognized convention exists regarding the calculation of percent identity, the claim is vague and indefinite.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi
12/27/2005

ALI R. SALIMI
PRIMARY EXAMINER